

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TENNESSEE  
WESTERN DIVISION**

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**SMITH & NEPHEW, INC.,**

**Plaintiff,**

**v.**

**No. 2:04-cv-03027-STA-cgc**

**NEW HAMPSHIRE INSURANCE  
COMPANY, ALLIED WORLD ASSURANCE  
COMPANY LTD., ZURICH INSURANCE  
COMPANY, GERLING KONZERN  
ALLGEMEINE VERSICHERUNGS AG,  
and ASSICURAZIONI GENERALI S.p.A.,**

**Defendants.**

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**ORDER GRANTING DEFENDANTS' JOINT MOTION TO COMPEL PRODUCTION  
OF ALL DOCUMENTS REGARDING THE SAME SUBJECT MATTER AS THE  
DOCUMENTS PLAINTIFFS PREVIOUSLY PROVIDED TO THE FDA**

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Before the Court is Defendants' Joint Motion to Compel Production of All Documents Regarding the Same Subject Matter as the Documents Plaintiffs Previously Provided to the Food and Drug Administration ("FDA") (Docket Entry "D.E." # 290). The instant motion was referred to United States Magistrate Judge Charmiane G. Claxton for determination. (D.E. #293). For the reasons set forth herein, the Court ORDERS that Rule 26 permits discovery of all documents of the same subject matter as those provided to the FDA subject to the Protective Order, but that it is not appropriate at this time to determine whether any asserted privilege has been waived pursuant to Rule 502 of the Federal Rules of Evidence. Further, the Court will hold a telephonic status conference on Thursday, May 26 at 10:00 a.m. regarding the in-camera review.

## I. Introduction

On December 22, 2010, Defendants' filed the instant Joint Motion pursuant to Rule 502(a) of the Federal Rules of Evidence. Defendants' Joint Motion requests that the Court compel production of all documents regarding the same subject matter as the documents Plaintiff previously provided to the FDA as part of the 2006 FDA Establishment Inspection Report ("2006 EIR")<sup>1</sup> that have heretofore been withheld from production on attorney-client privilege and work product grounds. Defendants assert that such production is required by Rule 502(a) of the Federal Rules of Evidence and by the District Judge's May 28, 2009 Order Affirming the Magistrate Judge's Order on Defendants' Motion to Compel<sup>2</sup>, which affirmed that "fairness requires that a party cannot be allowed to withhold some evidence on a matter while disclosing other evidence that is presumably more favorable."

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<sup>1</sup> The twenty-five page 2006 EIR describes a comprehensive three-day "for cause" inspection of Smith & Nephew's facility regarding the mactrotextured knee implant devices at issue in this case and contains an exhibit list of seventy-eight additional documents.

<sup>2</sup> The District Judge's May 28, 2009 Order considered, *inter alia*, (1) whether Plaintiff waived work product protection for documents it placed in an electronic workroom to which Defendants had access, and, if so, (2) whether the waiver applied only to those specific documents or whether Plaintiff's waiver constituted a general subject matter waiver as to other documents similar to those in the electronic workroom. The District Judge concluded that Plaintiff waived work product protection as to all documents in the electronic workroom by its failure to limit Defendants' access to the documents. Based upon the Sixth Circuit's subject matter waiver rule, the District Court concluded that Plaintiff waived both work-product protection and attorney-client privilege as to "any evidence on the same subject as the documents stored in the electronic workroom." See In re Columbia/HCA Healthcare Corp., 293 F.3d 289 (6th Cir. 2002); In re Grand Jury Proceedings October 12, 1995, 78 F.3d 251 (6th Cir. 1996); Edwards v. Whitaker, 868 F. Supp. 226 (M.D. Tenn. 1994). Furthermore, although Rule 502 had not been enacted until after the filing of the motions, the District Court concluded that the Magistrate Judge's Order was not inconsistent with Rule 502(a)'s fairness element. Thus, because the District Court determined that it is not clear what the newly adopted Rule 502 requires or how it affects the Sixth Circuit's broad subject matter waiver rule, the District Court concluded that the Magistrate Judge's Order was not clearly erroneous or contrary to Rule 502.

On January 10, 2011, Plaintiff responded that federal law does not require a subject matter waiver under the circumstances presented in the instant case. Smith & Nephew asserts that neither Rule 502 nor the District Court's May 28, 2009 Order require such disclosures of all material of the same subject matter as the 2006 EIR. On January 31, 2011, Defendants filed a Reply in Support of their Joint Motion to Compel (D.E. #297), and on February 4, 2011, Smith & Nephew filed a Sur-Reply in Opposition to Defendants' Joint Motion to Compel (D.E. #298). The Magistrate Judge held a hearing on March 11, 2011, at which time the parties were ordered to create a joint subject matter listing for the in-camera review. The parties filed their Joint Subject-Matter Listing for Purposes of In Camera Review on March 18, 2011 and filed memoranda on the proposed scope of the in-camera review on March 18, 2011 and March 24, 2011. The parties additionally submitted documents to the Magistrate Judge for purposes of in-camera review.

## II. Analysis

Rule 502(a) of the Federal Rules of Evidence provides as follows:

**(a) Disclosure made in a Federal proceeding or to a Federal office or agency; scope of a waiver**—When the disclosure is made in a Federal proceeding or to a Federal office or agency and waives the attorney-client privilege or work product protection, the waiver extends to an undisclosed communication or information in a Federal or State proceeding only if:

- (1) the waiver is intentional;
- (2) the disclosed and undisclosed communications or information concern the same subject matter; and
- (3) they ought in fairness to be considered together.

Fed. R. Evid. 502(a). The Explanatory Note to Subdivision (a) states that subject-matter waiver is “reserved for those unusual situations in which fairness requires a further disclosure of related, protected information, in order to prevent a selective and misleading *presentation of evidence* to the

disadvantage of the adversary.” Fed. R. Evid. 502, Explanatory Note to Subdivision (a)(quoting In re United Mine Workers of America Employee Benefit Plans Litig., 159 F.R.D. 307, 312 (D.D.C. 1994) (emphasis added). The Explanatory Note to Subdivision (a) also provides that “subject matter waiver is limited to situations in which a party intentionally *puts protected information into the litigation* in a selective, misleading or unfair manner.” Fed. R. Evid. 502, Explanatory Note to Subdivision (a) (emphasis added). Further, the Committee Letter states that Subdivision (a) “provides that if a waiver is found, it applies only to the information disclosed, unless a broader waiver is made necessary by the holder’s *intentional and misleading use* of privileged or protected communications or information.” Fed. R. Evid. 502, Committee Letter (emphasis added).

The District Court has already acknowledged that the application of newly enacted Rule 502 is a developing area of law and that there is little guidance as to how it should govern the discovery process. However, upon review of the Rule, the Court finds that it is not appropriate at this time to determine whether either attorney-client privilege or work-product protection has been waived. The question of waiver is more appropriately determined if and when either party attempts to present arguably privileged information as substantive evidence, either upon motion for summary judgment or at trial, because it is at this point in the litigation that the District Court would determine whether or not certain materials “ought in fairness to be considered together” to avoid a “selective and misleading presentation of evidence to the disadvantage of the adversary.” See Fed. R. Evid. 502 & Explanatory Note to Subdivision (a).

Instead, at this stage, the Magistrate Judge must determine what materials are discoverable. Discovery is guided by Rule 26 of the Federal Rules of Civil Procedure, which provides in general that parties “may obtain discovery regarding any nonprivileged matter that is relevant to any party’s

claim or defense” but further provides that “[f]or good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.” Fed. R. Civ. P. 26(b)(1).

In the instant case, discovery is guided by a Protective Order, which insures that there are appropriate protections in place for the discovery of privileged materials. Accordingly, the sole task for this Court is to determine what materials are “relevant to the subject matter involved in the action,” as is the common task under Rule 26. In this situation, the parties will have the opportunity to present as substantive evidence any of the materials provided to the FDA. Because such a presentation may at that time lead to a finding of subject-matter waiver under Rule 502, any materials of the same subject matter may be relevant to the subject matter involved in the action. Thus, the Court finds that for discovery purposes, all materials of the same subject matter as the materials provided to the FDA should be discoverable subject to the Protective Order. Such a process should allow for the parties to best prepare for any eventualities regarding the presentation of evidence at summary judgment or at trial but does not waive any privilege that may be asserted at the appropriate time. The Court will hold a telephonic status conference to discuss the in-camera review of the submitted documents on Thursday, May 26 at 10:00 a.m. At the status conference, the parties should advise what documents still need to be reviewed by the Court following the entry of this order.

**IT IS SO ORDERED** this 19th day of May, 2011.

s/ Charmiane G. Claxton  
CHARMIANE G. CLAXTON  
UNITED STATES MAGISTRATE JUDGE